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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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NUTTER MCCLENNEN & FISH LLP
SEAPORT WEST
155 SEAPORT BOULEVARD
BOSTON, MA 02210-2604

EXAMINER	
WOLF, MEGAN YARNALL	
ART UNIT	PAPER NUMBER
3738	

NOTIFICATION DATE	DELIVERY MODE
09/16/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No.	Applicant(s)	
	10/828,841	KLADAKIS ET AL.	
	Examiner	Art Unit	
	Megan Wolf	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-18,20-23,25,27-37,39 and 41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-18,20-23,25,27-37,39 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/19/10 has been entered.

Response to Arguments

2. Applicant's arguments filed 7/19/10 have been fully considered but they are not persuasive. Applicant argues that Malaviya does not disclose or teach that any portions of the device include at least one channel configured to communicate biological materials to a tissue defect in the meniscus. However, paragraph 13 of Malaviya discloses that the material must be porous enough to permit remodeling. Paragraph 148 of Malaviya further discloses that during a recovery period after surgery body fluids such as blood and synovial fluids as well as cells infuse into the implant and begin the remodeling process. Because applicant has not clearly defined the channels, the examiner considers the pores in the material of Malaviya to be channels that communicate biological materials to the defect as discussed in paragraph 148.

Applicant argues that the device of Malaviya cannot extend to the synovium because Malaviya teaches that a radially outer portion of the original meniscus is maintained. However, the examiner maintains that because the claims are for a device

as opposed to the method of using the device, the device need only be capable of use as claimed. In the instant case the meniscal repair device is entirely capable of being placed such that it extends to the synovium. Applicant further argues that if the device were placed in contact with the synovium it would no longer "conform to the space into which it is inserted such that the surrounding tissue of the remaining meniscus is in contact with the device." The examiner disagrees and believes this interpretation of Malaviya is too narrow. If the device of Malaviya were extended to the synovium, it could still be in contact with the side portions of the surrounding tissue of the remaining meniscus such that it does not go against the teachings of Malaviya as applicant alleges. Applicant argues that modification of the device of Malaviya as set forth by the examiner wherein the device is positioned adjacent to the synovium as opposed to the meniscal rim would change the principle of operation of Malaviya. However, no modification of Malaviya (with regard to the positioning of the device) is required because the claim is for the device and not a method of positioning the device. Further, Malaviya distinctly shows portions of the cover including the tabs shown in fig.41 that extend beyond the meniscus to the synovium. As these tabs are an extension of the flap, and are formed of the same material, they are capable of communicating biological materials to the tissue defect.

Regarding the combination of Malaviya and Vallee, applicant argues that Malaviya cannot be positioned in contact with the synovium. The examiner maintains that Malaviya is capable of being positioned in contact with the synovium for the same reasons discussed above. Malaviya discloses in paragraph 134 that it is known that the

meniscal-synovial junction is highly vascularized which is why tears heal better in this region. Vallee goes one step further and specifically teaches that it is known that tears may be healed if they communicate with the synovium. Therefore, one of ordinary skill in the art would have been motivated to combine the teachings of Vallee with the method disclosed by Malaviya and extend the device to the synovium in order to improve the healing capabilities. Further, since Malaviya discloses that the junction of the meniscus and synovium is highly vascularized, extending the implant just slightly further to the synovium would have been obvious in view of Vallee which teaches that this region is known for its healing ability. Doing so still allows the device to conform to the space into which it is inserted such that the surrounding tissue of the remaining meniscus is in contact with the device, including the side portions of the space (anterior and posterior edges with respect to the meniscus) shown in at least figures 1 and 41. Applicant further argues that modification of the device of Malaviya as set forth by the examiner wherein the device is positioned adjacent to the synovium as opposed to the meniscal rim would change the principle of operation of Malaviya. The examiner disagrees because the principle of operation of Malaviya as taught in paragraph 134 is to place the device in proximity to the highly vascularized meniscal-synovial junction to facilitate healing and remodeling. As modified by the examiner the device of Malaviya in view of Vallee would still conform to a space into which it is inserted such that it contacts the surrounding tissue of the remaining meniscus.

Regarding the combination of Malaviya, Vallee, and Li, applicant argues that Li does not suggest depositing fibrin clot material in contact with the synovium. This

limitation is not claimed, and Li was used to show that it is commonplace to rasp a space prior to implanting an implant in order to channel the blood supply into the area which is the initial phase of healing. Since the combination of Malaviya and Vallee discloses an implant placed in a space formed in the meniscus and extending to the synovium, it would have been obvious in view of Li to rasp this prepared space.

Regarding the rejections of claims 20 and 34-37 over the combination of Malaviya in view of Schwarz and the rejections of claims 39 and 41 over the combination of Malaviya in view of Vallee and Schwartz, applicant argues that the device of Schwartz is contained within a porous film such that one would modify the mass within the conduit flap of Malaviya rather than the flap itself. However, the porous film covering the insert is only one embodiment disclosed by Schwartz, and other embodiments are directed to an insert that is a porous film (col.3, ll.46-56; fig.20) which has the claimed void volume. Schwartz teaches a high void volume for the purpose of allowing for invasion of cells to regenerate the articular cartilage. Since Malaviya discloses a porous device for regenerating articular cartilage, it would have been obvious to use the void volume taught by Schwartz to ensure cells could invade the implant.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 2, 4-18, and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malaviya et al. 2003/0036797 (hereafter referred to as Malaviya).

Re claims 1 and 2, Malaviya discloses a biocompatible meniscal repair device, comprising a biocompatible tissue repair scaffold 60 adapted to be placed in contact with a defect in a meniscus and a cell growth conduit flap 58,64 attached to the tissue repair scaffold (figs. 8-16,22-55,63,64), the cell growth conduit flap capable of contacting a tibial surface, extending to the synovium, and having at least one channel (pores in the material) configured to communicate biological materials, including cells and nutrients, to a tissue defect in the meniscus (pars.13, 19, 148). Malaviya discloses the invention substantially as claimed and also discloses that the covers may have a density in the range of 872-884 mg/cc and that the properties of the covers may be varied depending on the process conditions to yield a density of 4-994 mg/cc (par.142). While Malaviya does not specifically disclose that the density of the covers is in the range of about 150mg/cc to 350mg/cc, it would have been obvious to modify the density of the flap since Malaviya does disclose methods of generating different densities as well as various values for densities and it has been held that it is not inventive to discover the optimum or workable ranges by routine experimentation and would be an obvious extension of prior art teachings (In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), MPEP 2144.05 II A).

Re claim 4, ECM is bioabsorbable.

Re claims 5 and 6, see par.182.

Re claims 7, 8, 10, 30, 31, and, 33, see par.36.

Re claims 9 and 32, Malaviya discloses that the scaffold and flap can include glycolide and L-lactide as explained above with respect to claims 7 and 8. Malaviya also discloses that any copolymer used in implants can be utilized (par.36). Malaviya does not specifically state that this device uses the copolymer of glycolide and L-lactide, however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the material with the copolymer of glycolide and L-lactide, as it is well known in the art to use the copolymer of glycolide and L-lactide and Malaviya states that copolymers can be used.

Re claim 11, Malaviya discloses that viable tissue is disposed within the scaffold (biologically derived agents, par.159 - the agents can be tissue as described in par.33). It is inherent that the tissue would integrate with the native tissue.

Re claims 12 and 13, Malaviya discloses that the scaffold can contain within it bioactive agents (par.159) including growth factors or other agents that stimulate cell growth (par.32).

Re claim 14, the cell growth conduit flap and scaffold can be formed from a single piece, as they both can be made from the same large sheet of ECM material and cut as desired to form the specific parts. The process by which the device is made is not germane to the issue of patentability of the device itself.

Re claims 15-17, figs. 33-35 show that the flap and scaffold are oriented together such that they are substantially perpendicular. Figures 55, 63, and 64 show the scaffold and flap oriented with respect to each other such that they may be considered to form shapes of a "T" or "L".

Re claim 18, all figures show that the flap is less thick than the scaffold.

5. Claims 21, 25, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malaviya in view of Vallee et al. 4,952,404 (hereafter referred to as Vallee). Malaviya discloses the invention substantially as claimed and as discussed above, and further discloses the step of fixing the device in position (figs. 33, 38, 40, 41). Malaviya also discloses that the peripheral rim of the meniscus at the menisco-synovial junction is highly vascular (par.134) and that regeneration is encouraged from the radially outer portions of the device to the inner portions of the device where the native tissue is less vascularized (par.24). However, Malaviya does not specifically disclose the step of positioning a cell growth conduit flap in contact with the synovium.

Vallee teaches a method of promoting healing of meniscal tissue, in the same field of endeavor, and teaches that it is known that meniscal tears may be healed if they communicate with the synovial membrane (col.1, ll.15-19).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the placement of the device of Malaviya such that the covers contact the more vascularized synovium in order to promote healing of the meniscus as taught by Vallee.

6. Claims 22, 23, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malaviya in view of Vallee as applied to claims 21 and 25 above, and further in view of Li et al. 4,790,819 (hereafter referred to as Li). Malaviya discloses the invention substantially as claimed and as discussed above but does not disclose the step of rasping the meniscus or synovium before positioning the cell growth conduit flap.

Li discloses in the background of the invention, first paragraph, that the initial phase in wound repair is a fibrin clot. They further state that this is absent in meniscal tears, and as such the synovium and meniscus are regularly rasped in surgical procedures to channel the blood supply into the area to be able to form a clot (therefore the step would be before positioning any devices in the tear, as it should be the initial phase of the healing).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the step of rasping the meniscus and synovium before placing the cell growth conduit flap in position in view of the teaching of Li, in order to provide an increased blood supply to help promote wound repair.

7. Claims 20 and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malaviya in view of Schwartz et al. 6,468,314 (hereafter referred to as Schwartz). Malaviya discloses the invention substantially as claimed and as discussed above and Malaviya further discloses that the material that forms all parts of the device should be porous enough to permit remodeling (par.13). However, Malaviya does not specifically teach a void volume in the range of about 50-95%.

Schwartz teaches a cartilage repair device, in the same field of endeavor, wherein the void volume is at least 95% for the purpose of allowing for an invasion of cells to regenerate the articular cartilage.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify porous device of Malaviya to have a void volume of about 95% as taught by Schwartz in order to allow for cells to penetrate the device and regenerate the

meniscus. Regarding the claimed void volume range of about 50-95% it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), MPEP 2144.05 II A). Therefore, it would have been obvious to modify the void volume of Malaviya based on the general conditions taught by Schwartz.

8. Claims 39 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malaviya in view of Vallee as applied to claims 21 and 25 above, and further in view of Schwartz. Malaviya in view of Valle discloses the invention substantially as claimed and as discussed above and Malaviya further discloses that the material that forms all parts of the device should be porous enough to permit remodeling (par.13). However, Malaviya in view of Vallee does not specifically teach a void volume in the range of about 50-95%.

Schwartz teaches a cartilage repair device, in the same field of endeavor, wherein the void volume is at least 95% for the purpose of allowing for an invasion of cells to regenerate the articular cartilage.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify porous device of Malaviya to have a void volume of about 95% as taught by Schwartz in order to allow for cells to penetrate the device and regenerate the meniscus. Regarding the claimed void volume range of about 50-95% it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (In re Aller, 220

F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), MPEP 2144.05 II A). Therefore, it would have been obvious to modify the void volume of Malaviya based on the general conditions taught by Schwartz.

Conclusion

9. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Wolf whose telephone number is (571)270-3071. The examiner can normally be reached on Monday-Friday 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. W./
Examiner, Art Unit 3738
/David H Willse/
Primary Examiner, Art Unit 3738